K072418

Section 5

510(K) SUMMARY

SEP 12 2007

Prepared: July 27, 2007

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR Part 807.92.

The assigned 510(k) number is: _____.

1. **Submitter's Identification:**

Respironics New Jersey, Inc.
41 Canfield Road
Cedar Grove, New Jersey
07009
Phone: 973 571 2608
Fax: 973 857 9521
Contact Name: Lauren Ziegler
e-mail: lauren.ziegler@respironics.com

Establishment Registration Number :2243193

Official Correspondent:

Lauren Ziegler
Director, QA, RA, and Clinical Affairs
41 Canfield Road
Cedar Grove, NJ 07009
Phone: 973-571-2608
Fax: 973-857-9521
e-mail: Lauren.ziegler@respironics.com

2. **Name of the Device:**
OptiChamber Advantage Anti-Static Valved Holding Chamber
Common Name or Classification Name (21 CFR Part 807.87) of Device:
Metered Dose Inhaler Spacer, 21 CFR Part 868.5630

3. **Predicate Device Information:**

Identification of legally marketed device which we claim substantial equivalence to:

Respironics New Jersey, Inc.
41 Canfield Road
Cedar Grove, New Jersey 07009

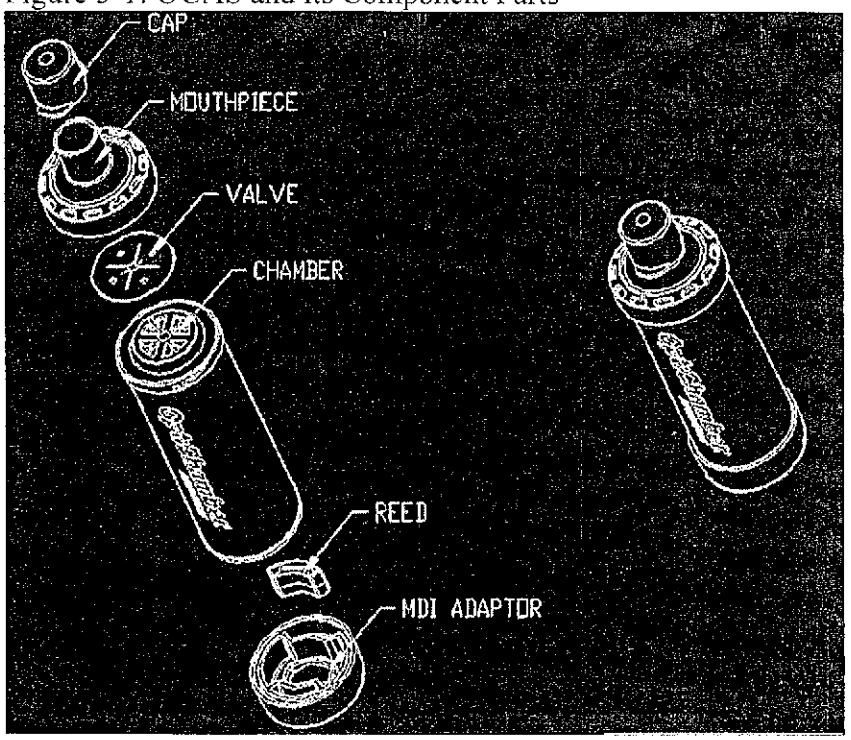
AeroChamber Z-Stat Plus Valved Holding Chamber
K052332
Trudell Medical International
725 Third Street
London, Ontario, CA N5V 5 G4

4. **Device Description:**

OptiChamber Advantage Anti-Static (OCAS) is a Class II device. It is a valved holding chamber for use with metered dose inhalers (MDIs).

The OCAS is a valved holding chamber utilizing the same operating principles as the OptiChamber (K962822) and the AeroChamber Z-Stat (K052322). The difference between the OCAS and the OptiChamber is that, like the AeroChamber Z-Stat, the OCAS is made of an anti-static plastic material.

Figure 5-1: OCAS and its Component Parts



The objective in using a spacer is to have patients breathe in only those aerosol particles that are of a respirable Mass Median Aerodynamic Diameter (MMAD) such that a therapeutically beneficial amount of drug is able to reach the lungs and a minimal amount of drug is deposited in the oropharynx. To

accomplish this, valved holding chambers slow down the aerosol exiting the MDI, evaporate the carrier propellant and gravimetrically retain larger, unrespirable particles.

To use OCAS, the protective caps from both the MDI and the mouthpiece of the device are removed. The MDI (including the actuator) is inserted into the opening in the MDI adaptor at the distal end of the device. The MDI and OCAS combination should be shaken vigorously just prior to inhalation. The patient should exhale normally through the OCAS mouthpiece. The one-way valve prevents the patient's breathe from entering the chamber as air is exhaled through vents in the mouthpiece. The patient actuates the MDI into the OCAS and immediately inhales.

OptiChamber Advantage Anti-Static Valved Holding Chamber has a chamber and mouthpiece made of anti-static material. Non-anti-static valved holding chambers must be washed prior to use. The use of anti-static material in the aerosol path allows an unwashed device to produce the same drug delivery as a washed device.

5. Intended Use:

OptiChamber Advantage Anti-Static Valved Holding Chamber is intended to be used in combination with Metered Dose Inhalers (MDIs) for respiratory drug delivery. This device, as is the case with other spacer devices, is intended to leave larger non-respirable drug particles within the device and allows smaller respirable particles to be delivered to the lungs.

6. Comparison to Predicate Devices:

The subject (OCAS) and predicate devices (OptiChamber, K962822 and AeroChamber Z-Stat, K052322) are indicated for the same intended use. The difference between the OCAS and the OptiChamber is the material for the housing and top. The anti-static material used for the mouthpiece and chamber of OCAS allow the user to get the same aerosol delivery without washing the device prior to use. This anti-static characteristic is common to OCAS to the the predicate AeroChamber Z-Stat. The performance characteristics of OCAS and AeroChamber Z-Stat are substantially equivalent. Both devices are portable and lightweight.

7. Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:

The OCAS and the predicate device, the AeroChamber Z-Stat, were tested for particle size distribution and aerosol characterization according to methodology outlined in the FDA "Reviewer Guidance for Nebulizers, metered Dose Inhalers, Spacers and Actuators, 10/93". Testing

documentation shows that the aerosol characteristics of the OCAS and the AeroChamber Z-Stat are substantially equivalent.

8. Discussion of Clinical Tests Performed:

Not Applicable

9. Conclusions:

We have demonstrated that the OptiChamber Advantage Anti-Static Valved Holding Chamber is as safe and effective as a predicate device, the AeroChamber Z-Stat, presently on the market, based on substantially equivalent aerosol characterization testing. The performance of the OCAS before and after washing are also substantially equivalent and this is reflected in the labeling differences between the predicate OptiChamber and the OCAS. The three devices are also substantially equivalent in terms of their operating principle and indications for use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 12 2007

Respironics New Jersey, Incorporated
C/O Mr. Ned Devine
Responsible Third Party Official
Underwriters Laboratories, Incorporated
333 Pfingsten Road
Northbrook, Illinois 60062

Re: K072418
Trade/Device Name: OptiChamber Advantage Anti-Static Valved Holding Chamber
Regulation Number: 21 CFR 868.5630
Regulation Name: Nebulizer
Regulatory Class: II
Product Code: CAF
Dated: August 23, 2007
Received: August 28, 2007

Dear Mr. Devine:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

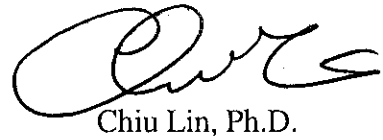
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4618. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): _____

Device Name: OptiChamber Advantage Anti-Static Valved Holding Chamber

Indications for Use:

OptiChamber Advantage Anti-Static Valved Holding Chamber is intended to be used in combination with Metered Dose Inhalers (MDIs) for respiratory drug delivery. This device, as is the case with other spacer devices, is intended to leave larger non-respirable drug particles within the device and allows smaller respirable particles to be delivered to the lungs.

Prescription Use ____X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Number: K072418